

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/010121

International filing date (day/month/year)
25.03.2005

Priority date (day/month/year)
06.05.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/05

Applicant
BOSTON SCIENTIFIC SCIMED, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010121

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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PCT/US2005/010121

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	32
	No: Claims	1-31,33-41
Inventive step (IS)	Yes: Claims	
	No: Claims	1-41
Industrial applicability (IA)	Yes: Claims	1-41
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 Reference is made to the following document:

- D1: US-A-5 954 761 (MACHEK ET AL) 21 September 1999 (1999-09-21)
- D2: US-A-5 860 974 (ABELE ET AL) 19 January 1999 (1999-01-19)
- D3: US-A-5 170 802 (MEHRA ET AL) 15 December 1992 (1992-12-15)
- D4: US 2002/151949 A1 (DAHL ROGER ET AL) 17 October 2002 (2002-10-17)
- D5: US-A-6 136 021 (TOCKMAN ET AL) 24 October 2000 (2000-10-24)
- D6: EP-A-0 861 676 (MEDTRONIC CARDIORHYTHM) 2 September 1998 (1998-09-02)
- D7: US-A-5 782 239 (WEBSTER, JR. ET AL) 21 July 1998 (1998-07-21)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** is not new in the sense of **Article 33(2) PCT**.

Document D1 discloses (the references in parentheses applying to this document):

An expandable intravascular medical device, comprising (see figs. 3-5):

- a tubular body including an integrated, electrically conductive, resilient support structure (40A, 40B) that forms a plurality of electrically conductive regions, the tubular body further including at least one electrically insulative element disposed between the conductive regions (see column 4, lines 17-24); and
- at least one lead (38) electrically coupled to at least one of the conductive regions.

2.2 For the sake of completeness, it is pointed out that also the teaching of e.g. documents D2 (see figs. 4, 5) and D7 (see fig. 1) take away the novelty (Article 33(2) PCT) of claim 1.

3 CLAIMS 2-41

Independent **claims 12, 18, 22, 31, 37** and dependent **claims 2-11, 13-17, 19-21, 23-30, 32-36, 38-41** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (**Article 33(2) and (3) PCT**), because their features are either already disclosed in documents D1-D7 (reference is made to the passages cited in the international search report), or because

their features are a normal option for a skilled person.